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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,067

11/10/2004

Roch Boivin

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,067	BOIVIN ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-22,37,38,43-45,66,84-88,108 and 119-132 is/are pending in the application.
- 4a) Of the above claim(s) 84-88,108 and 119-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-22,43 and 66 is/are rejected.
- 7) ☒ Claim(s) 37,38,44,45 and 127-132 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1,3-22, 37, 38, 43-45, 66, 84-88, 108 and 119-132 are currently pending in the instant application. Applicants have cancelled claims 39-42, 46 and 81-83 and added new claims 130-132 in an amendment filed on March 10, 2009. Claims 1, 3-22, 43 and 66 are rejected; claims 37, 38, 44, 45 and 127-132 are objected and claims 84-88, 108 and 119-126 are withdrawn from consideration.

I. *Response to Arguments/Remarks*

Applicants' amendment filed on March 10, 2009, has overcome the rejection of claims 9-21, 37-46 and 66 under 35 USC 112, second paragraph for the phrase "having the structure"; the rejection of claims 1, 3-22, 37-46, 66, 81-83 and 127-129 under 35 USC 112, second paragraph as being indefinite for the phrase "may form"; the rejection of claims 39-41 under 35 USC 112, first paragraph as failing to comply with the enablement requirement; the rejection of claims 42 and 46 under 35 USC 112, first paragraph as failing to comply with the enablement requirement; the rejection of claims 81-83 under 35 USC 112, first paragraph as failing to comply with the enablement requirement; and the objection of claims 1,3-22, 37-46, 66, 81-83 and 127-129 as containing non-elected subject matter. The above rejections and objection have been withdrawn.

Applicants have failed to overcome the ODP rejection of claims 1, 3-22, 43 and 66 as being unpatentable over 10/657,910. Applicants state "should the claims be considered allowable, the provisional nonstatutory ODP rejection will be removed"

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however the Examiner wants to point out that is true if the instant application is the earlier filed application. The instant application is not considered the “earlier filed case” because the earliest filing date claimed under 120, 121 or 365(c) is March 7, 2003 which is the same as copending application 10/657,910. Therefore, Applicants have to filed a terminal disclaimer to overcome the ODP rejection.

II. Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 10, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

III. Rejection(s)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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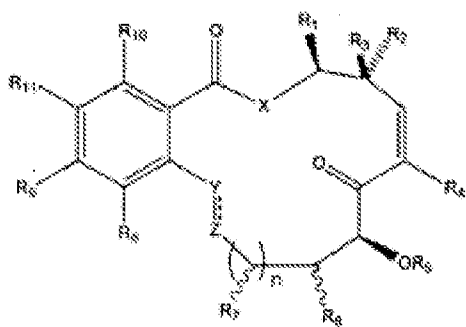
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-22, 43 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 10 of copending US application 10/657,910. This is a provisional obviousness-type double patenting rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Applicants' elected subject matter is a compound of formula I



, wherein R₁ is hydrogen, aliphatic,

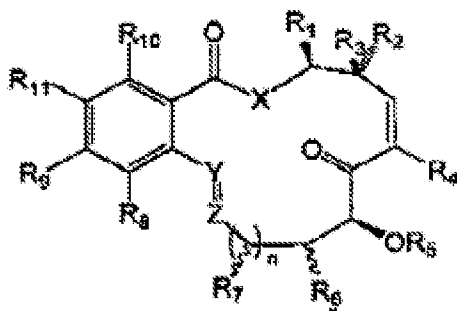
heteroaliphatic, alicyclic or aryl; R₂ and R₃ are each independently hydrogen, halogen, hydroxyl, protected hydroxyl, aliphatic, heteroaliphatic, alicyclic, or aryl; or R₁ and R₂, when taken together, may form a substituted or unsubstituted, saturated or unsaturated cyclic ring of 3 to 8 carbon atoms or R₁ and R₃, when taken together, may form a substituted or unsubstituted, saturated or unsaturated cyclic ring of 3 to 8 carbon atoms; R₄ is hydrogen or halogen; R₅ is hydrogen, an oxygen protecting group or prodrug

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moiety; R_6 is hydrogen, hydroxyl or protected hydroxyl; n is 0-2; R_7 or each occurrence, is independently hydrogen, hydroxyl or protected hydroxyl; R_8 is hydrogen, halogen, hydroxyl, protected hydroxyl, alkyloxy or an aliphatic moiety optionally substituted with hydroxyl, protected hydroxyl, SR_{12} or $NR_{12}R_{13}$; R_9 is $NR_{12}R_{13}$; wherein R_{12} and R_{13} are independently for each occurrence, hydrogen, aliphatic, heteroaliphatic, alicyclic, aryl or a protecting group; R_{10} is hydrogen, hydroxyl, protected hydroxyl, amino or protected amino; R_{11} is hydrogen, hydroxyl or protected hydroxyl; X is absent or is O, NH, N-alkyl, CH_2 or S and Y and Z are defined as in claim 1.

Determining the Scope and Content of the Copending Application

Claim 1 of the copending application claims a pharmaceutical composition comprising a compound of the formula



, wherein R_1 is hydrogen, aliphatic,

heteroaliphatic, alicyclic or aryl; R_2 is methyl; R_3 is hydrogen, halogen, hydroxyl, protected hydroxyl, aliphatic, heteroaliphatic, alicyclic, heteroalicyclic, aryl or heteroaryl moiety; or R_1 and R_3 , when taken together, may form a substituted or unsubstituted,

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saturated or unsaturated cyclic ring of 3 to 8 carbon atoms; R_4 is hydrogen or halogen; R_5 is hydrogen or an oxygen protecting group; R_6 is hydrogen, hydroxyl or protected hydroxyl; n is 0-2; R_7 or each occurrence, is independently hydrogen, hydroxyl or protected hydroxyl; R_8 is hydrogen, halogen, hydroxyl, protected hydroxyl, alkyloxy or an aliphatic moiety optionally substituted with hydroxyl, protected hydroxyl, SR_{12} or $NR_{12}R_{13}$; R_9 is hydrogen, halogen, hydroxyl, protected hydroxyl, OR_{12} ; SR_{12} , $NR_{12}R_{13}$, $X_1(CH_2)_pX_2-R_{14}$ or is lower alkyl optionally substituted with hydroxyl, protected hydroxyl, halogen, amino, protected amino or $-X_1(CH_2)_pX_2-R_{14}$; wherein R_{12} and R_{13} are independently for each occurrence, hydrogen, aliphatic, heteroaliphatic, alicyclic, heteroalicyclic, aryl, heteroaryl or a protecting group, or R_{12} and R_{13} , taken together may form a saturated or unsaturated cyclic ring containing 1 to 4 carbon atoms and 1 to 3 nitrogen or oxygen atoms and each of R_{12} and R_{13} are optionally further substituted as defined in claim 1; R_{10} is hydrogen, hydroxyl, protected hydroxyl, amino or protected amino; R_{11} is hydrogen, hydroxyl or protected hydroxyl; X is absent or is O, NH or CH_2 and Y and Z are defined as in claim 1.

**Ascertaining the Differences Between the Instant Application and the
Coping Application**

The claims of the instant application are drawn to a broader compound genus than the claims of the coping application, which encompass the elected subject matter of the coping application. In the instant application, X is absent or is

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O, NH, N-alkyl, CH₂ or S whereas in the copending application X is O.

Finding Prima Facie Obviousness

As mentioned above, the genus compound of the instant application encompasses the narrower genus compound in the copending application. Therefore, one of ordinary skill in the art would be motivated to prepare and claim the scope of the compounds in the instant application since the scope already in the copending application is encompassed by the scope of the elected subject matter in the instant claims. As a result, the claims are rejected under obviousness-type double patenting.

IV. Objections

Dependent Claim Objections

Dependent Claims 37, 38, 44, 45 and 127-132 are objected to as being dependent upon a rejected based claim.

V. Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626